

REMARKS

Claim Amendments

Claims 1-2, 5-11, 16-18, 21-23, 25-29, 42-43 and 47 are pending in this application.

Applicants have amended claims 1, 16 and 18. The claim amendments do not add any new matter to the specification.

Telephone Interview

Applicants thank the Examiner for participating in a telephone interview with the Undersigned on May 11, 2006 to discuss the enablement and written description rejections. The claim amendments made herein are a result of this interview and Applicants appreciate the Examiner's assistance.

Enablement

Claims 1-2, 5-11, 16-18, 21-23, 25-29, 42-43 and 47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Office Action states that the reasons for this rejection are of record in the Office Action mailed 6/6/05.

Applicants respectfully traverse the Examiner's rejection. The claims as currently pending differ from the claims pending at the time the previous Office Action (mailed on 6/6/05) was issued. The currently pending claims do not require the identification or the synthesis of a particular carbohydrate epitope. Instead, the claims merely require the use of an antibody that binds to an epitope comprising a peptide (consisting of the amino acid sequence DTRPAP) and a carbohydrate.

As previously submitted, a person of skill in the art could readily make antibodies which bind to an epitope comprising a peptide (consisting of the amino acid sequence DTRPAP) and a carbohydrate. This could be done in basically two steps. The first step involves immunizing an animal using glycosylated MUC-1 (or a cell expressing glycosylated MUC-1) as an antigen, harvesting and immortalizing antibody-secreting splenocytes, and subsequently screening and selecting clones which secrete antibodies which bind to an epitope consisting of the amino acid

sequence DTRPAP. The second step involves further screening to determine whether the antibody (or antigen binding fragment thereof) which binds to the amino acid sequence DTRPAP binds preferentially to glycosylated MUC-1. As taught in the specification, an antibody that binds preferentially to glycosylated MUC-1 recognizes an epitope comprising a carbohydrate (see page 30, lines 7-10). Preferential binding to glycosylated MUC-1 can be determined by comparing binding of antibody to glycosylated MUC-1 as found on tumor cells or secreted into the serum of cancer patients and to the binding of the antibody to MUC-1 that has been stripped of its glycosylation, or that has been produced in the presence of glycosylation inhibitor. These methods described in this paragraph are disclosed in Examples 1 and 12 of the specification and are routine in the art.

In view of the arguments presented herein, Applicants respectfully request that the Examiner withdraw this rejection.

Written Description

Claims 1-2, 5-11, 16-18, 21-23, 25-29, 42-43 and 47 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner states that "[t]he claims are drawn to the epitope comprising a peptide and a carbohydrate, wherein the peptide comprises the amino acid sequence DTRPAP" and that "there is insufficient written description for this language."

In order to expedite prosecution, Applicants have amended the claims to recite the use of an antibody or antigen binding fragment thereof that binds to an epitope of MUC-1, "the epitope comprising a peptide and a carbohydrate, wherein the peptide consists of the amino acid sequence DTRPAP." This amendment obviates the Examiner's rejection. For the record, Applicants clarify that the amended claim language still encompass the use of an antibody or antigen binding fragment thereof that binds to the amino acid sequence DTRPAP regardless of whether this amino acid sequence is present as a part of MUC-1.

In view of the arguments presented herein, Applicants respectfully request that the Examiner withdraw this rejection.

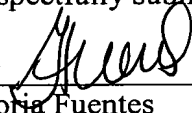
Conclusion

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

Applicants believe no fee, other than the fee for the enclosed Petition for an extension of time and the enclosed Notice of Appeal, is due with this response. However, if an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. AREX-P03-002 from which the undersigned is authorized to draw.

Dated: July 6, 2006

Respectfully submitted,

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